## REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested.

### I. Status of the Claims

Claims 1 - 10 are pending in the subject application.

Claims 1 - 10 were rejected.

In the current response, claim 1- 6 and 8 - 10 are amended for clarification. Claim 7 is canceled. Claims 11 - 14 are newly added. No new matter is entered.

Applicants will sequentially address the issues raised by the Examiner.

### II. New Claims

New claim 11 is added. Support for claim 11 can be found in line 1 through line 3 of paragraph [0023], in line 1of paragraph [0033] and in line 1 and line 2 of paragraph [0044] of the Specification.

New claims 12 and 13 are added. Support for these claims can be found in line 1 of paragraph [0024] through line 3 of paragraph [0029], in line 1 of paragraph [0040] through line 10 of paragraph [0042], in line 5 of paragraph [0045] through line 11 of paragraph [0048] (Examples 1.A., 1.B., and 1.C.) and in line 12 of paragraph [0048] through line 7 of paragraph [0054] (Example 2) of the Specification, and Figures 1 through 6.

New claim 14 is added. This claim is supported by original claim 5 and by paragraph [0027], [0042], and [0046].

### III. Specification

In the specification, the paragraphs [0001], [0023] and [0050] have been amended to correct obvious errors due to misprints without adding new matters. The following is a

quotation of MPEP 2163.07, II OBVIOUS ERRORS. "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction." In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

In paragraphs [0001], [0023] and [0050], the word "pentacylic triterpenids" should be "pentacyclic triterpenoids". Applicants respectfully ask the Examiner to allow these amendments to correct the obvious errors that the applicants made in the specification of their original application.

## IV. Claim Objections

Claim 3 was objected to because of typographical error.

Claim 3 has been corrected by replacing the correct word "triterpenoids" to the word "triterpenids", which is a typographic error the Applicants made in their original claim.

## V. The 35 U.S.C. §112 Claim Rejections

A. Claim 2

Claim 2 was rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 2 has been amended for further clarification.

B. Claim 8 -10

Claim 8 – 10 were rejected under 35 U.S.C. §112, second paragraph, as allegedly having not set forth any steps involved in the method/process.

Applicants have amended Claim 8 to recite "a method of treating a disease characterized as hypertension, comprising administering to a subject suffering from said disease a therapeutically effective amount of total triterpenoid sapogenins as defined in claim 1, …". Supporting descriptions for Claim 8 can be found in line 1 through line 4 of paragraph [0031], in line 9 through line 12 of paragraph [0044] and in line 14 of paragraph [0056] through line 2 of paragraph [0069] of the Specification (Example 4 with Table 1 through Table 4). The Applicants disclose the procedure of treating hypertension. The concentration of total triterpenoid sapogenins in aqueous solution with

a solutizer, the dosage per body weight, the administer method of the drug and the therapeutic results are disclosed in detail in Example 4.

Applicants have amended Claim 9 to recite "a method of protecting skin or hair, comprising administering to a subject a therapeutically effective amount of total triterpenoid sapogenins as defined in claim 1, …". Supporting descriptions for Claim 9 can be found in line 1 through line 3 of paragraph [0032], in line 14 of paragraph [0044] and in line 6 of paragraph [0094] through line 6 of paragraph [0115] of the Specification (Example 6 with Table 9). The Applicants disclose procedures of protecting skin or hair. The concentration of total triterpenoid sapogenins in DMEM solution, the dosage for daily cosmetics for treating skin cells and the results of protecting the skin and hair from antioxidant-induced damage are disclosed in detail in Example 6.

Applicants have amended Claim 10 to recite "a method of preventing or treating a disease characterized as carcinoma, comprising administering to a subject suffering from said disease a therapeutically effective amount of total triterpenoid sapogenins as defined in claim 1,…". Supporting descriptions for Claim 10 can be found in line 5 and line 8 of paragraph [0031], in line 9 of paragraph [0044] and in line 3 of paragraph [0069] through line 5 of paragraph [0094] of the Specification (Example 5 with Table 5 through Table 8). The Applicants disclose procedures of treating carcinoma. The concentration of total triterpenoid sapogenins in solution for treating various tumor cells and carcinoma cells, the dosage for the treatment and the therapeutic results in comparison with other current anti-tumor therapy are disclosed in detail in Example 5.

## VI. The 35 U.S.C. §101 Claim Rejections

Claim 8 – 10 were rejected under 35 U.S.C. §101, as allegedly "having not set forth any steps involved in the process, … resulting in a claim which is not a proper process claim under 35 U.S.C. 101."

Applicants have amended Claim 8 to recite a method of treating hypertension disease. Disclosures that support Claim 8 can be found in line 1 through line 4 of paragraph [0031], in line 9 through line 12 of paragraph [0044] and in line 14 of

paragraph [0056] through line 2 of paragraph [0069] of the Specification (Example 4 with Table 1 through Table 4). The Applicants disclosed a novel procedure of treating hypertension. In their controlled experiments they discovered and invented a method of preparing the total triterpenoid sapogenins, the therapeutic dosages, and the treatment results in details.

Applicants have amended Claim 9 to recite a method of protecting skin and hair. Disclosures that support Claim 9 can be found in line 1 through line 3 of paragraph [0032], in line 14 of paragraph [0044] and in line 6 of paragraph [0094] through line 6 of paragraph [0115] of the Specification (Example 6 with Table 9). The Applicants disclosed a novel procedure of protecting skin and hair. In their controlled experiments they discovered and invented a method of preparing the total triterpenoid sapogenins, the therapeutic dosages, and the experiment results in details.

Applicants have amended Claim 10 can be found in line 5 and line 8 of paragraph [0031], in line 9 of paragraph [0044] and in line 3 of paragraph [0069] through line 5 of paragraph [0094] of the Specification (Example 5 with Table 5 through Table 8). The Applicants disclosed a novel procedure of treating tumor. In their controlled experiments they discovered and invented a method of preparing the total triterpenoid sapogenins, the therapeutic dosages, the comparison of their treatment with other anticancer drugs, and the treatment results in details.

## VII. The 35 U.S.C. §102/103 Claim Rejections

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by or, under 35 U.S.C. §103(a) as obvious over Ohmoto et al. (Shoyakugaku Zasshi (1974), 28(1), pages 1-6). Respectfully, the Applicants wish to express their view about differences between their invention and Ohmoto et al. reference, so that the Examiner may reconsider his rejection of claim 1 – 3.

For ease of review, Applicants reproduce amended claim 1 herein below:

> "A composition comprising a substantial amount of total triterpenoid sapogenins extracted from bamboo, wherein the substantial amount is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as

a standard, said total triterpenoid sapogenins comprising 5-35% friedelin and 1-10% lupenone as determined by GC-MS."

Support for the amendments can be found throughout the specification, and more specifically, for example, in paragraphs [0021] through [0023].

The Examiner asserts: "Ohmoto et al. disclose a composition comprising triterpenoid sapogenins and related compounds that are extracted from bamboo (Arundinarieae) of Gramineae plants wherein said composition comprises friedelin, lupenone and other pentacyclic triterpenoids (see abstract). It should be noted that Arundinaria is a genus of bamboo commonly known as canes. Ohmoto et al do not explicitly disclose the total % of triterpenoid sapogenins and the % of friedelin and lupenone in their composition. But, the silence of Obmoto et al. does not mean that their composition does not contain the same said total % of triterpenoid sapogenins and % of friedelin and lupenone."

The courts have ruled that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegall Bros. v. Union Oil Co. of California, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Also, "The identical invention must be shown in as complete detail as is contained in the … claim." Richardson v. Suzuki Motor Co., 868 F. 2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Applicants of the present invention claims a composition, in which the total triterpenoid sapogenins extracted from bamboo are enriched and two components of the total triterpenoid sapogenins: friedelin and lupenone are especially enriched. Claim 1 explicitly recites a composition comprising 10-90% of total triterpenoid sapogenins, in which there are 5-35% friedelin and 1-10% lupenone. (paragraphs [0046] through [0055]: Examples 1.A., 1.B.,1.C. and Example2).

The compound disclosed in Ohmoto et al. reference is distinctively different from the composition disclosed by the Applicants.Applicants carefully studied the content of the cited Ohmoto et al. reference. The following table summarizes the composition disclosed in the cited Ohmoto et al. reference:

| | Bamboo | Triterpenoid | Friedelin | Lupenone |
|---|---|---|---|---|
| Ref. of Ohmoto | A. Arundinaria simonii Riviere | Not disclosed | 0.42/32 =1.31% | 0 |
| | B. Chimonobambusa quadrangularis Makino | Not disclosed | 0.011/42 =0.03% | 0 |
| | C. Phyllostachys bambusoides Sieb et Zucc | Not disclosed | 0.3/28.5 =1.05% | 3.0/28.5 =10.53% |
| | D. Phyllostachys bambusoides Sieb et Zucc var aurea Makino | Not disclosed | 1.87/162.5 =1.15% | 0.75/162.5 =0.05% |
| | E. Phyllostachys nigra Munro var henonis Stapf | Not disclosed | 0.22/19.2 =1.15% | 0 |
| | F. Sasa japonica Makino | Not disclosed | 0.93/73 =1.27% | 0 |
| | G..Sasa ramose Makino | Not disclosed | 0.185/55.5 =0.03% | 0 |
| | H.Sasa veitchii Rehd | Not disclosed | 6.51/157 =4.1% | 0 |

As it can be seen from this table, the reference of Ohmoto et al. does not teach or suggest the composition comprising a substantial amount of total triterpenoid sapogenins extracted from bamboo, wherein the substantial amount is 10-90%. Therefore, Ohmoto's reference does not render 102 rejection over claim 1 of the present invention.

One of the reasons that the Applicants' composition differs from the composition of the reference of Ohmoto et al. is the methods for preparing the two compositions are substantially different. As described in paragraph [0019] (Background) of the present invention, traditional methods in the art are less selective than the methods disclosed in the present invention. Since bamboo materials contain a great variety of compounds such as fatty acids, flavones, proteins, lipids, vitamins, aliphatic hydrocarbon, carbohydrates, cytochromes, triterpenoids and so on, the content of triterpenoids is usually very low in the composition extracted by traditional methods such as the method used in the cited

reference of Ohmoto et al.. Therefore, it would NOT have been obvious at the time the invention was made to a person having ordinary skill in the art to derive a composition with substantial amount of total triterpenoid sapogenins by reading Ohmoto's reference. Applicants respectfully request the Examiner reconsider and withdraw 103 rejection of claim 1.

Claims 2 and 3 are dependent from claim1, and are therefore also patentably distinct in view of cited Ohmoto reference for at least the same reasons as those set forth with respect to claim1. Applicants respectably request the Examiner reconsider and withdraw rejections of claims 2 and 3.

## VIII. The 35 U.S.C. §103 Claim Rejections

The Examiner rejected claims 4-7 under 35 U.S.C. §103(a) as being unpatentable over the reference of Staack Reis Machado et al. (EP 1122259 A2) (referred as Machado) The Examiner states:

> "It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in order to use them to treat conditions such as rheumatoid diseases, based on factors such availability, cost, convenience and/or need.
>
> …It should be noted that merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105, U.S.P.Q.233 (C.C.P.A.1955)."

Applicants carefully reviewed the cited reference and respectfully submit that the cited reference does not teach or suggest the present invention. Applicants obviate these rejections with the following amendments and remarks.

Claim 4 is amended as the following to show criticality of the present invention:

"A method of extracting total triterpenoid sapogenins from bamboo comprising:

(a) selecting bamboo material from the group consisting of Phyllostachys, Bambusa and Dendrocalamus genus of Gramineae family;

(b) preparing bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material;

(c) extracting free triterpenoid sapogenins from the bamboo shaving powder by mixing the bamboo shaving powder with supercritical $CO_2$ fluid and an entrainer in the amount of 5 –15 % (v/v) of $CO_2$ until the free triterpenoid sapogenins is dissolved in the $CO_2$ fluid at temperature 50 – 60 degree C and pressure 25 – 35 Mpa;

(d) separating total triterpenoid sapogenins from the $CO_2$ fluid containing free triterpenoid sapogenins by changing the temperature of the $CO_2$ fluid to 35 – 45 degree C and the pressure to 5 – 10 Mpa to gasify the $CO_2$;

(e) collecting a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone."

Comparison between the amended claim 4 of the present invention and Machado's reference will show many distinctive differences between the present invention and the cited reference.

Machado's invention is directed to "Extraction process wherein a supercritical fluid, or the same fluid in the liquid state under near critical conditions is used to extract the ceroid fraction of **cork smoker wash solids** and to recover long chain aliphatic alcohols and diterpenoid and triterpenoid compounds contained in said ceroid fraction." (claim 1, Machado).

The raw material taught by Machado's reference belongs to ***tree family***: "The raw material is virgin cork resulting from cork tree pruning operation, dead trees and cork residues from several industrial operations." (Machado [0002])

The target compounds extracted by Machado's method are aliphatic alcohols (Line 18 – 19 of Paragraph [0025], Machado). The raw material suitable for extracting long chain aliphatic alcohols is not any plant. According to Machado: "As far as these

compounds are concerned, ***cork smoker wash solids is a unique material***, because it contains these compounds in extraordinarily high amounts ***compared to what is currently found in nature***." (Line 26 – 28 of Paragraph [0016], Machado).

In contrast, the amended claim 4 in the present invention recites a step of collecting a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone from the extration process. The raw material taught by the present invention is "bamboo material from the group consisting of Phyllostachys, Bambusa and Dendrocalamus genus of Gramineae family", as recited in claim 4. Bamboo plant belongs to ***grass family*** (Encyclopedia Britannica), which is distinctively different from a cork tree.

Improper hindsight reasoning should not be applied in support of an obviousness rejection. MPEP 2145.X.A. "It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." Interconnect Planning Corp. v. Feif, 774 F .2d 1132,1141, 227 USPQ 543, 550 (Fed. Cir. 1985); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553,220 USPQ 303,312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record conveyor suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher"). Id.

Machado discloses a method of extracting long chain aliphatic alcohols and diterpenoid and triterpenoid compounds from cork trees without addressing the problem addressed by the present invention. Applicant respectfully submits that it is an improper hindsight reconstruction based on the Applicant's Specification in support of the obviousness rejection.

Furthermore, Machado's "cork smoker wash solids" was prepared by steaming and cooking cork granules at ***400 degree C*** and then the cork agglomerate was formed. The ***steaming and cooking step*** used by Machado is necessary for the preparation of "cork smoker wash solids", since collecting water vapor and then getting settled "cork

smoker wash solids" are necessary (Machado Reference, line18 – 30 of paragraph [0002].)

In the present invention, the amended clam 4 recites a step of "preparing bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material". The claim is supported by various descriptions in the present invention. For example, in paragraph [0027]: "In a preferred embodiment, the material is bamboo powder with the granularity of 10-20 meshes,…" An example is also provided in paragraph [0046]: "Example 1.A. ….5.5 kg bamboo shaving powders of Phyllostachys nigra var. henonis in Gramineae at the granularity of 20 meshes were put into the extraction kettle. …"

The Applicants respectfully submit that there is no similarity between steaming and cooking cork granules at 400 degree C and preparing bamboo shaving powder having a granularity. Therefore, it would not have been obvious at the time the invention was made to a person having ordinary skill in the art to derive the method of preparing bamboo shaving powder from the steaming and cooking method taught by Machado's reference.

It is thus respectfully noted that to establish a case of prima facie obviousness, the Examiner must meet three criteria. First, the Examiner must show that the references upon which she or he relied teach every limitation of the current claimed invention, In re Royka 490 F.2d 981, 985 (C.C.P.A.1974). Second, the Examiner must show that there is some suggestion or motivation in the references themselves, or within the knowledge of one of ordinary skill in the art, to alter or combine references to arrive at the claimed invention. Lastly, the Examiner must show that there is a reasonable expectation of success in altering or combining the references, and that this expectation of success is found in the references as well. In re vaeck 947 F.2d 488, 493 (Fed. Cir. 1991).

Based on the above discussions, it is respectfully contended that the present invention, as recited in the amended claim 4 meets the test of patentability over the cited reference under 35 U.S.C. §103 (a). Machado does not disclose, teach or suggest ALL of the limitations recited in the amended claim 4. Therefore, the present invention, as

recited in the amended claim 4 is distinctively different from Machado's teaching. Reconsideration and withdrawal of the rejection is respectfully requested.

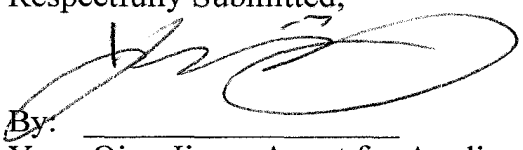
Claims 5 and 6 are dependent from claim4, and also patentably distinct in view of cited Machado's reference for at least the same reasons as those set forth with respect to claim 4. Applicants respectfully request the Examiner reconsider and withdraw rejections of claims 5 and 6.

**IX. Conclusion**

The applicants respectfully request reconsideration of the claims in view of the amendments and remarks made herein. A notice of allowance is earnestly solicited.

Should the Examiner believe that further discussion of any remaining issue would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,



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